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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,031	03/15/2004	Tara Lynn Bielski	1592-473	6868

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EXAMINER	
MAHYERA, TRISTAN J	

ART UNIT	PAPER NUMBER
4173	

NOTIFICATION DATE	DELIVERY MODE
12/07/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No.	Applicant(s)	
	10/800,031	BIELSKI ET AL.	
	Examiner	Art Unit	
	Tristan J. Mahyera	4173	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-66* is/are pending in the application.

4a) Of the above claim(s) *61-65* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-60 and 66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *04/11/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I in the reply filed on 10/03/2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Status of Claims

Claims 1-66 are pending. Claims 61-65 are withdrawn as being drawn to the non-elected invention. Claims 1-60 and 66 are examined on the merits.

Specification

The disclosure is objected to because of the following informalities: The use of the trademarks METHOCEL®, METALUSE®, KELACID®, MANUCOL® and KELTONE® have been noted in this application. These trademarks should be capitalized wherever they appear and be accompanied by the generic terminology and mark.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-49 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over SHAMAR et al. (US 2006/0002997, see PTO-892) in view of PATEL et al. (US 4,772,473, see PTO-1449).

SHAMAR teaches a controlled release dosage form that includes a sustained release portion and an immediate release portion wherein the sustained release portion includes nitrofurantoin monohydrate and the immediate release portion includes macrocrystalline nitrofurantoin. See e.g. paragraphs [0004], [0016] and [0025]. The sustained release portion is in the form of a powder, granule, compact or tablet and the immediate release portion is in the form of a powder or granule. See e.g. paragraph [0009]. The sustained release polymers provide a therapeutically acceptable level of nitrofurantoin for more than twelve hours, while the immediate release portion allows for rapid absorption to quickly achieve therapeutic plasma levels. See e.g. paragraph [0021]. The sustained release and immediate portions contain pharmaceutically acceptable excipients such as diluents, binders, lubricants and colors. See e.g. [0028] and [0030]. The dosage form may be in tablet or capsule form. See e.g. [0031]. The portions are preferably separate layers, however the portions can be varied and mixed. See e.g. [0033] lines 6-9. Suitable excipients in either the immediate or sustained layer includes hydroxypropyl methylcellulose, sodium alginate, dibasic calcium phosphate, microcrystalline cellulose, lactose, starch, magnesium stearate and colors. See e.g. paragraph [0029]. The tablet is encapsulated within a single capsule or the tablet and powders or granules are encompassed in a capsule. See e.g. paragraph [0044]. The immediate release and sustained release portion are independently mixed or formed and need not be combined into a capsule. See e.g. [0014] and [0015]. The formulation is optionally coated. See e.g. [0029] last sentence. Example 2 teaches the use of 75mg of nitrofurantoin monohydrate and 25mg of macrocrystalline nitrofurantoin per

capsule representing about 10% and about 70% of each portion respectively. See e.g. [0045]. Example 2 further teaches magnesium stearate is about 0.01% and lactose and starch are about 45% of the portion whereas hypromellose is about 7%. SHAMAR additionally teaches the use of hypromellose from between about 0.01% to about 15%. See e.g. [0024]. The ratio of the immediate release portion to the sustained release portion is about 1:2.7. See e.g. Examples 1 & 2.

SHAMAR does not explicitly teach the use of alginic acid or the percentage of each compound in the components.

PATEL teaches a combination sustained release/rapid release pharmaceutical capsules for oral administration of nitrofurantoin containing separate layers of a particulate mixture and a second particulate mixture are contained in a capsule shell. See e.g. column 3 lines 40-45. Other pharmaceutical carriers may be added to provide capsules having the desired characteristics. See e.g. column 8 lines 48-50. Alginic acid is taught as a pharmaceutical carrier. See e.g. column 9 line 3.

Claims 50-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over SHAMAR.

SHAMAR teaches the step of admixing nitrofurantoin monohydrate with sustained release polymers and pharmaceutically acceptable excipients. See e.g. paragraph [0033]. SHAMAR further teaches the step of admixing macrocrystalline nitrofurantoin with pharmaceutically acceptable excipients and filling into a capsule. See e.g. paragraph [0032].

The percentage by weight of each compound/excipient in the first or second component of the formulation is obvious to one of ordinary skill in the art at the time of the instant invention because PATEL states that pharmaceutical carriers may be added to provide capsules having the desired characteristics. See e.g. column 8 lines 48-50. Furthermore, adjusting the percent of a compound in the formulation is simple optimization and known to a skilled pharmacologist. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969).

It would have been obvious to one of ordinary skill in the art at the time of the invention to practice a controlled release dosage form that includes a sustained release portion and an immediate release portion wherein the sustained release portion includes nitrofurantoin monohydrate and the immediate release portion includes macrocrystalline nitrofurantoin because SHAMAR teaches it is within the skill of the art

to use pharmaceutically acceptable excipients to improve the capsule or table characteristics and because PATEL teaches it is within the skill of the art to use alginic acid as a pharmaceutically acceptable excipient to improve the capsule or table characteristics. One would have been motivated to do so in order to receive the expected benefit, as suggested by SHAMAR and actually exemplified by PATEL. Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention.

Conclusion

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tristan J. Mahyera whose telephone number is 571-270-1562. The examiner can normally be reached on Monday through Thursday 9am-4pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/TJM/

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614